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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,583	08/31/2001	Andrew Robinson	1581.0840001/RWE	9616

26111 7590 11/21/2006

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EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Notice of Allowability	Application No. 09/942,583	Applicant(s) ROBINSON ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/17/06*.

2. ☒ The allowed claim(s) is/are *1-8 and 22; now renumbered 1-9 respectively*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *attached* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

N. M. Minnifield
Primary Examiner
Art Unit: 1645

SUPPLEMENTAL EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rob Esmond, 32893 on November 17, 2006.

The application has been amended as follows:

1. (Previously presented) A method of preparing a composition, said composition comprising an isolated heterologous gene product and a pharmaceutically acceptable carrier, said method comprising the steps of:

(a) inserting a gene coding for the heterologous gene product into an expression vector;

(b) transforming said expression vector into a commensal *Neisseria*;

(c) expressing said heterologous gene product in said commensal *Neisseria*;

(d) isolating said heterologous gene product from the *Neisseria* of (c); and

(e) combining the heterologous gene product of (d) with the pharmaceutically acceptable carrier, wherein said heterologous gene product is selected from (1) a product of a gene of a non-*Neisserial* organism and (2) a product of a gene of a pathogenic *Neisseria*.

2. (Original) The method of claim 1, wherein said commensal *Neisseria* is selected from the group consisting of *N. cinerea, N. lactamica, N. elongata, N.*

flava, N. flavescens, N. polysaccharea, N. sicca, N. mucosa, N. perflava and *N. subflava.*

3. (Previously presented) The method of claim 1, wherein the heterologous gene product is the product of a gene of a pathogenic *Neisseria.*

4. (Previously presented) The method of claim 3, wherein the heterologous gene product is (a) transferrin binding protein; (b) a Cu,Zn-SOD; (c) an NspA; (d) a porin; (e) an outer membrane protein; or a fragment of any of (a) - (e).

5. (Previously presented) The method of claim 1, wherein said isolating comprises:

(i) suspending said commensal *Neisseria* cells in the presence of detergent;

(ii) incubating the suspension;

(iii) extracting a protein fraction from the cells; and

(iv) isolating the heterologous gene product from the protein fraction.

6. (Previously presented) The method of claim 5, wherein the protein fraction is of molecular weight 50 kDa or lower when measured by SDS-PAGE.

7. (Previously presented) The method of claim 5, wherein the protein fraction is of molecular weight from 40 kDa to 90 kDa when measured by SDS-PAGE.

8. (Previously presented) The method of claim 5, wherein the protein fraction is of molecular weight at least 80 kDa when measured by SDS-PAGE.

9 - 21. (Canceled).

22. (Previously presented) A method according to claim 1, wherein step (d) comprises (i) isolating an outer membrane vesicles from the *Neisseria* of step (c), and (ii) isolating said heterologous gene product from said outer membrane vesicles; and wherein said heterologous gene product comprises an outer membrane protein or is directed to the outer membrane of said *Neisseria* by a signal sequence.

23-25. (Canceled).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
November 17, 2006

CLEAN COPY OF ALLOWED CLAIMS

1. A method of preparing a composition, said composition comprising an isolated heterologous gene product and a pharmaceutically acceptable carrier, said method comprising the steps of:

(a) inserting a gene coding for the heterologous gene product into an expression vector;

(b) transforming said expression vector into a commensal *Neisseria*;

(c) expressing said heterologous gene product in said commensal *Neisseria*;

(d) isolating said heterologous gene product from the *Neisseria* of (c); and

(e) combining the heterologous gene product of (d) with the pharmaceutically acceptable carrier, wherein said heterologous gene product is selected from (1) a product of a gene of a non-*Neisserial* organism and (2) a product of a gene of a pathogenic *Neisseria*.

2. The method of claim 1, wherein said commensal *Neisseria* is selected from the group consisting of *N. cinerea, N. lactamica, N. elongata, N. flava, N. flavescens, N. polysaccharea, N. sicca, N. mucosa, N. perflava* and *N. subflava.*

3. The method of claim 1, wherein the heterologous gene product is the product of a gene of a pathogenic *Neisseria.*

4. The method of claim 3, wherein the heterologous gene product is (a) transferrin binding protein; (b) a Cu,Zn-SOD; (c) an NspA; (d) a porin; (e) an outer membrane protein; or a fragment of any of (a) - (e).

5. The method of claim 1, wherein said isolating comprises:

(i) suspending said commensal *Neisseria* cells in the presence of detergent;

(ii) incubating the suspension;

(iii) extracting a protein fraction from the cells; and

(iv) isolating the heterologous gene product from the protein fraction.

6. The method of claim 5, wherein the protein fraction is of molecular weight 50 kDa or lower when measured by SDS-PAGE.

7. The method of claim 5, wherein the protein fraction is of molecular weight from 40 kDa to 90 kDa when measured by SDS-PAGE.

8. The method of claim 5, wherein the protein fraction is of molecular weight at least 80 kDa when measured by SDS-PAGE.

22. A method according to claim 1, wherein step (d) comprises (i) isolating an outer membrane vesicles from the *Neisseria* of step (c), and (ii) isolating said heterologous gene product from said outer membrane vesicles; and wherein said heterologous gene product comprises an outer membrane protein or is directed to the outer membrane of said *Neisseria* by a signal sequence.